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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/543,371	04/04/00	KALLURI	R 1440.1027005

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HM22/0605

EXAMINER

CLEMENS, K

ART UNIT	PAPER NUMBER
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1644

DATE MAILED:

06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/543,371

Applicant(s)

KALLURI, RAGHURAM

Examiner

Karen Clemens

Art Unit

1644

-- Th MAILING DATE of this communication appears on th cover sheet with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____ .
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☒ The proposed drawing correction filed on 16 February 2001 is: a) ☒ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2/13/01 .
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____ .
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: .

DETAILED ACTION

1. Claims 1-7 are currently pending and under consideration.
2. The title of the invention should convey to those skilled in the art the subject matter of the instant invention. A title which gives reference to fragments of the $\alpha 3$ (IV) NC1 domain of Collagen (Tumstatin) would better describe the subject matter of the claimed invention.
3. The abstract of the disclosure fails to include the subject matter of the instant invention. An abstract which gives reference to fragments of the $\alpha 3$ (IV) NC1 domain of Collagen (Tumstatin) would better describe the subject matter of the claimed invention.
4. The filing date of claims with limitations which include the $\alpha 3$ (IV) NC1 domain of Collagen from amino acids 54-124 and 185-203, of claims 4 and 7, respectively, is deemed to be the filing date of the instant application, filed 4/4/00, as no support is found for the said polypeptide fragments in priority documents 60/126175, 60/089689 or 09/335224.
5. The following is a quotation of the first paragraph of 35 U.S.C. §112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims 1-3 and 5-6 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a first isolated non-Goodpasture fragment of $\alpha 3$ (IV)NC1 domain having the ability to bind the $\alpha_v\beta_3$ integrin in an RGD-independent fashion and/or the ability to inhibit proliferation of endothelial cells wherein the fragment is unable to inhibit tumor cell proliferation. The

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instant claims are further drawn to a second isolated non-Goodpasture fragment of $\alpha 3(IV)NC1$ domain having the ability to bind the $\alpha_v\beta_3$ integrin in an RGD-independent fashion and/or bind endothelial cells and/or inhibit the proliferation of tumor cells and /or which is unable to inhibit the proliferation of endothelial cells.

However, Applicant's disclosure is limited to the $\alpha 3(IV)NC1$ domain fragments of amino acids 54-124 and 185-203 of SEQ ID NO:10. The disclosure is further limited to Tum1(N53) -amino acids 54-244 which does not possess the Goodpasture antigen and Tum2 (333) -amino acids 1-124 of SEQ ID NO:10 containing the Goodpasture antigen (Goodpasture antigen proposed to reside within amino acids 1-40), which both bind to the $\alpha_v\beta_3$ integrin in an RGD-independent fashion and inhibit the proliferation of endothelial cells but are unable to inhibit melanoma cell proliferation. The disclosure is further limited to Tum4 of amino acid sequence 181-244 of SEQ ID NO:10 which does not possess the Goodpasture antigen, has the ability to bind the $\alpha_v\beta_3$ integrin in an RGD-independent fashion, binds to endothelial cells but is unable to inhibit their proliferation and inhibits the proliferation melanoma cells.

In the instant case, however, there is no described or art-recognized correlation or relationship between the *structure* of the instant invention, an isolated non-Goodpasture fragment of $\alpha 3(IV)NC1$ and the *functional* ability to bind the $\alpha_v\beta_3$ integrin in an RGD-independent fashion and/or the ability to inhibit proliferation of endothelial cells wherein the fragment is unable to inhibit tumor cell proliferation. In addition no described or art-recognized correlation or relationship is described between the *structure* of the instant invention, an isolated non-Goodpasture fragment of $\alpha 3(IV)NC1$ and the *functional* ability to bind the $\alpha_v\beta_3$ integrin in an RGD-independent fashion and/or bind endothelial cells and/or inhibit the proliferation of tumor cells and /or which is unable to inhibit the proliferation of endothelial cells, upon which the invention is based

Consequently, one of skill in the art would not envisage, based on the instant disclosure, the claimed *genus* of $\alpha 3(IV)NC1$ fragments other than the disclosed fragments of amino acids 54-124 and 185-203 and Tum1, Tum2, Tum3 and Tum4 of SEQ ID NO:10.

The claimed *genus* of $\alpha 3(\text{IV})\text{NC1}$ fragments may be adequately described if there is a sufficient description of a *representative number of species*. To satisfy the disclosure of a "representative number of species" will depend on whether one of skill in the art would recognize that the applicant was in possession of the necessary *common attributes or features of the elements possessed by the members of the genus in view of the species disclosed*. The claimed genus may also be adequately described through disclosure of sufficient *relevant, identifying characteristics* to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. "*Relevant, identifying characteristics*" includes structure or other physical and/or chemical properties, functional characteristics *coupled* with a known or disclosed correlation between function and structure, or a combination of such identifying characteristics sufficient to show that applicant was in possession of the claimed genus. However, given this definition, the disclosed fragments of amino acids 54-124 and 185-203 and Tum1, Tum2, Tum3 and Tum4 of SEQ ID NO:10 do not represent the entire *genus* of $\alpha 3(\text{IV})\text{NC1}$ fragments with the aforementioned attributes.

Consequently, the claimed invention is not described in such a way as to reasonably convey to one of ordinary skill in the art that the inventor, at the time the application was filed, had possession of the invention. See *Regents of the University of California v. Eli Lilly & Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicant is also directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. §102(b) as being anticipated by Kalluri et al. (J. Biol. Chem. 271(15):9062-9068, 1996, see IDS, PTO Form 1449). Kalluri et al. teach an isolated non-Goodpasture

fragment of $\alpha 3(\text{IV})\text{NC1}$ which comprises (having) the fragments of amino acids 54-124 and 185-203 of SEQ ID NO:10 (see page 9066 and figure 4 in particular).

Therefore, the reference teachings thus anticipate the claimed invention.

6. Claims 5-7 are rejected under 35 U.S.C. §102(b) as being anticipated by Han et al. (J. of Biol. Chem. 272(33):20395-20401, 1997, see IDS, PTO Form 1449). Han et al. teach an isolated non-Goodpasture fragment of $\alpha 3(\text{IV})\text{NC1}$ which comprises 185-203 of SEQ ID NO:10 (see abstract in particular).

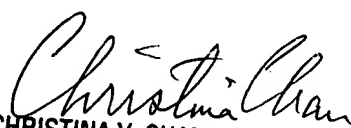
Therefore, the reference teachings thus anticipate the claimed invention.

7. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Clemens whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:00 AM to 5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Karen Clemens, Ph.D.
Patent Examiner
Technology Center 1600
June 1, 2001


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